

Remarks

Specification

The specification has been amended to include a benefit claim to international application No. PCT/SG99/00023, filed March 22, 1999 to bring the specification in compliance with 37 CFR § 1.78.

This priority claim was made in the transmittal letter of this application to the USPTO on November 22, 2000 (compliance with §371 as of June 18, 2001) and was recognized in the filing receipt mailed September 7, 2001. Applicants submit this amendment in accordance with OG Notice of January 22, 2002, which approves the entry of such an amendment under the circumstances specified without petition. Entry of this amendment is respectfully requested.

Claims

Claims 1-62 are pending in the present applications. Claims 7-12, 16, 20, 24 and 28-53 are withdrawn from consideration. Claims 1-3 are allowed, claim 58 is objected to, claims 4-6, 13-15, 17-19, 21-23, 25-27, 54-57 and 59-62 have been rejected. Claims 3, 5, 15, 19, 23 and 27 have been amended to specify that the coding region starts at nucleotide 80 of SEQ ID NO:1. This amendment is supported by Figure 2. Claims 63-76 have been added.

Rejections under 35 U.S.C. §112, second paragraph

On page 2, the Office rejects claims 18, 22-23 and 26-27 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

In particular, the Office considers the recitation of “a nucleic acid sequence” indefinite. The Office notes that replacing “a” with “the” in these claims would obviate

this rejection.

In response, Applicants have amended these claims as suggested by the Office.

Rejections under 35 U.S.C. §112, first paragraph

Written Description

Also on page 2, the Office continues to reject claims 4-6 as well as new claims 54-57 and 59-62, under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

On pages 4 to 6, the Office provides its reasoning. In particular, the Office expresses it's concerns about the term "moderately stringent conditions" in claims 4 and 5 and the claims dependent therefrom. The Office alleges that the claimed genus encompasses a multitude of nucleic acid molecules which encode a multitude of proteins completely unrelated to SEQ ID NO:4, the function of which is unclear. The Office also notes that no conserved region of SEQ ID NO:1 or 2 has been identified. On the bottom of page 5, the Office states that "[a]pplicants' mere recitation of a desired function, in the absence of any proof that the broad genus contains sequences conferring that function, is insufficient."

In response, Applicants have amended claim 4 to eliminate the reference to hybridization and stringency conditions. The claim now solely relies on sequence identity. The case law and the written description guidelines require a description of sufficient, relevant identifying characteristics so that a person skilled in the art would recognize that the inventor had possession of the claimed invention (MPEP §2163, II). Applicants have provided as relevant identifying characteristics the combination of the sequences recited in the claims combined with the function of the claimed nucleic acid.

The written description requirement for a claimed genus may be satisfied in a number of ways, including by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, **or** by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. See, University of California v. Eli Lilly, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

Applicants note that the Office, referring to page 21 of Applicant's response of July 11, 2003, asserts that Applicants allegedly questioned the ability of a gene with over 80% sequence similarity to SEQ ID No. 1 to actually encode a protein involved in meiocyte formation.

Applicants submit that, in the section of the response the Office refers to, all Applicants did was to note that the discussed reference (Rounsley et al.) lacked any disclosure as to the involvement of the sequence in meiocyte formation in a plant and thus did not disclose all the elements of the claimed invention as required for a 35 U.S.C. §102 reference. Applicants respectfully submit that this can not be equated with Applicants questioning of whether or whether not the disclosed sequence actually does or does not participate in meiocyte formation in a plant.

Enablement

Also on page 2, the Office continues to reject claims 4-6 and new claims 54-57 and 59-62 under 35 U.S.C. §112, first paragraph, for lack of enablement.

On page 3, the Office continues to reject claims 13-15, 17-19, 21-23 and 25-27 under 35 U.S.C. §112, first paragraph, for lack of enablement.

On pages 6 and 7, the Office expresses its continued concerns about the breadth of the claims and alleges that the specification lacks guidance for a person

skilled in the art to make or use the invention.

Enablement rejection of claims 4-6 and new claims 54-57 and 59-62

Applicants have amended claim 4 as discussed in the context of the written description requirement. Applicants believe that these amendments address the Office's concerns regarding the breadth of the claims.

Applicants note that on page 2, the Office alleges that the specification is enabling for nucleic acids from *Arabidopsis thaliana*, but not enabling for the nucleic acids as claimed.

Applicants have previously referred the Office for a description of how to use and make the invention of the rejected claims to pages 5, 34 and 35 and Examples 1-4 of the specification.

However, the Office continues to argue that there is insufficient guidance provided in the specification of how to make and use the invention.

Applicants attach for the Office's review an article by Meinke et al. describing the high acceptance of *Arabidopsis thaliana* in the scientific community as a model plant. The article reports that the research of *Arabidopsis thaliana* could be extrapolated as far as to the cellular mechanisms of non-plant organisms (*Meinke et al., Arabidopsis thaliana: A Model Plant for Genome Analysis, Science Vol. 282:662-682 (October 1998)*). Accordingly, Applicants submit that this article supports that a disclosure of examples of *Arabidopsis thaliana* are readily extrapolated by the person skilled in the art.

The Office also relies in this rejection of claims 4-6, 54-57 and 58-62 on the Spielman reference.

Applicants submit that the invention of claims 4-6, 54-57 and 59-62 is directed to nucleotide sequences that are involved in meiocyte (microsporocytes and megasporocytes) **formation**. In contrast, Spielman's discusses developmental processes of a plant **after** meiocyte formation, that is during processes, in particular meiosis, that meiocytes undergo **after** meiocyte formation has been completed. The last paragraph on page 2645 of Spielman, to which the Office refers in its rejection, states: "Thus, from the time of **microsporocyte formation**, every cell division . . . involves a **change** in cell identity. Despite decades of research on pollen development, little is yet known about the mechanisms by **which these changes** occur" [emphasis added]. Thus, without admitting that Spielman supports in any way that post "meiocyte formation" transformations are associated with any uncertainties, Spielman's disclosure of any uncertainties in the developmental processes of a plant is not concerned with meiocyte formation and thus is irrelevant in the context of these claims.

Thus, Applicants respectfully submit that neither the references cited by the Office nor the technical reasoning provided by the Office support a prima facie case of lack of enablement of the rejected claims, as required by the applicable case law. In re Marzocchi, 169 USPQ 367, 370 (CCPA 1971). See also MPEP §2164.04.

Applicants notes that the Office alleges that Applicants admitted that Spielman et al teach a failure rate as high as 95%. This allegation is not correct. Spielman et al. describe mutant alleles of the gene TETRASPORE (TES) and their discovery that the TES locus plays an essential role in pollen development. Thus, all Applicants pointed out in the last response is that, even with the tes mutants that Spielman et al. use, they still were able to report a 5-50% success rate in producing mature seeds. This is quite high considering that these plants have a mutation in genes which has been found to be essential to microsporocyte cytokinesis following the nuclear divisions of male meiosis.

Enablement rejection of claims 13-15, 17-19, 21-23 and 25-27

Applicants have previously referred the Office to a description of how to use and

make the invention of claims 13-15, 17-19, 21-23 and 25-27 on pages 19-21 and example 7 of the specification.

Applicants would like to emphasize that the second reference that the Office cited to support its argument that plant transformation with the genes of the present invention is unpredictable, that is, the Schieffthaler reference, actually reports in September of 1999, the **successful** transformation of a plant with the NOZZLE gene (SPOROCYTELESS gene) of *Arabidopsis thaliana*. The transformation achieved the desired results. This teaching, by itself, thus strongly supports that the present invention is enabled.

The state of the prior art & the level of predictability in the art

The Office cited both Matsuoka et al. and Schieffthaler at al. to support its argument that plant transformation with homeotic genes is unpredictable.

Matsuoka discusses a homeobox sequence from rice. Transformation of Matsuoka's sequence into rice results in abnormal morphologies of the transgenic rice plant. This leads the author to conclude that the product of the isolated homeobox sequence is related to the plant's developmental process. Thus, Applicants respectfully submit that Matsuoka et al. do not attach any significance to the abnormal morphologies beyond their being an indication that the respective homeobox gene is in fact involved in a plant's developmental process.

Accordingly, Applicants submit that ectopic transformation with a homeobox sequence, the product of which is potentially only a **part** of an array of proteins involved in the developmental processes it helps to control (see first paragraph on page 1040 of Matsuoka), does not provide any evidence of unpredictability of the relevant art.

Schieffthaler, the second reference cited by the Office, does, as outlined above, transform a plant with the NOZZLE gene of *Arabidopsis thaliana*. The transformation is

successful and achieves the desired results.

The amount of direction provided by the inventor & the existence of working examples

Applicants submit that the present invention provides sufficient guidance and working examples as to how to make and use the claimed invention. The present disclosure includes working example 7 that teaches the transformation of Landsberg plants by vacuum infiltration. The specification also provides general guidance as to how to make the claimed invention, e.g., on pages 19-21. Accordingly, even if the art involved were, as the Office alleges and which Applicants deny, unpredictable, the specification provides sufficient direction and guidance of how to make the invention.

Thus, Applicants respectfully submit that neither the references cited by the Office nor the technical reasoning of the Office support a prima facie case of lack of enablement of the rejected claims, as required by the applicable case law. In re Marzocchi, 169 USPQ 367, 370 (CCPA 1971). See also MPEP §2164.04.

Rejections under 35 U.S.C § 102(b)

On page 3, the Office rejects claims 4-5 under 35 U.S.C. §102(b) as anticipated by Rounsley et al (Accession No. B67977).

Applicants respectfully submit that the “Rounsley” reference is a product of the Arabidopsis Genomic Sequencing Project of The Institute for Genomic Research (TIGR). The sequence is identified in the printout provided by the Office as “T25H20TR TAMU Arabidopsis thaliana genomic clone T25H20, DNA sequence.”

The sequence appears to represent the DNA of a clone end of T25H20, which is identified by the sellers of the clone as a “member of the 384 well format set of clones used by the sequencing project” (see enclosure). The sequence alignment shown in

the printout attached to the Office Action shows alignment between nucleotides 611 - 843 (531-763 of the coding region) and nucleotides 844-1020 (764 to 940 of the coding region) of Sequence ID NO: 1 and nucleotides 508-262 and 196-009 of the T25H20TR sequence.

Applicants submit that the Rounsley DNA represents a partial DNA sequence of the gene the inventors isolated and characterized. Applicants further submit that the sequence appears to furthermore represent a partial sequence of a random clone of DNA, which was performed without any appreciation that a gene of *Arabidopsis* was sequenced, much less which gene. Furthermore, Applicants submit that Rounsley does not even indicate that sequence T25H20TR is part of a coding region since it does not define a Open Reading Frame, as it excludes the start codon of the SPOROCYTELESS gene.

Furthermore, Applicants submit that the Rounsley et al. reference does not disclose all elements of the claimed invention, namely that the claimed sequences participate in meiocyte formation in a plant, as is required for a reference to anticipate a claim under 35 U.S.C. §102(b).

Applicants further note that Rounsley et al. does not disclose the claimed sequence by inherency. Applicants submit that, to the best of their knowledge, a sequence that lacks about 50% of the nucleic acid residues of the naturally occurring DNA, **by itself**, cannot encode a protein that has the function of the protein that is encoded by the corresponding full length DNA.

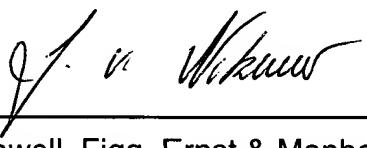
On page 4, the Office continues to reject claims 4-5, as well as new claims 54-56 and 59-62, under 35 U.S.C. §102(b) as being anticipated by Weigel et al and Pnueli et al. This rejection is traversed.

Applicants have amended the claims to further clarify the scope of the present invention, namely that the claimed nucleic acid has at least 70% sequence identity with the sequences specified under (a) and (b) of claim 4.

Also, Weigel et al and Pnueli et al. do not disclose all elements of the claimed invention, namely that the claimed sequences participate in meiocyte formation in a plant, as is required for a reference to anticipate a claim under 35 U.S.C. §102(b). Applicants submit that functional language in a claim cannot be ignored. It has been held that, as long as it did not render a claim indefinite, there is nothing inherently wrong with defining an invention by what it does, rather than what it is. In re Swinehart, 439 F.2d 210, 169 USPQ 226 (CCPA 1971). See also MPEP §2173.05(g).

In view of the foregoing amendments and discussions, Applicants respectfully submit that the pending claims are in condition for allowance.

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